
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

NAZIR KHAN,
IFTIKHAR KHAN

Plaintiffs,

v.

MERIT MEDICAL SYSTEMS, INC.,

Defendant.

FILED US District Court-UT
AUG 19 '21 PM03:42

Case No. 2:21-cv-00337-CMR

Magistrate Judge Cecilia M. Romero

RESPONSE IN OPPOSITION TO DEFENDANTS' RESPONSIVE PLEADING
ANSWER AND COUNTERCLAIM

1. The plaintiffs please request the Hon. Court to dismiss the responsive pleading answer and counterclaim under Rule 12(b)(6) and Rule 12(c) and grant summary judgement under FRCP Rule (56);

2. The plaintiffs request the Hon. Court for a declaratory judgement, that Merit Medical Systems Inc., has infringed upon claim 13 of patent No. US 8,747,344 B2 literally under 35 USC section 112, paragraph 6 "means-plus-function limitation" and section 112 paragraph 6 "equivalent", and an insubstantial difference test with respect to the connector disposition.

INTRODUCTION

Plaintiffs, Nazir Khan and Iftikhar Khan, invented the Hybrid Arteriovenous Shunt and patented under patent No. US 8,747,344 B2, dated June 10th, 2014. The device is used for hemodialysis, meaning, clearing the blood of toxins and the purified blood is deposited into the right atrium of the heart, whereby the purified blood travels into the entire body of patients with chronic renal failure. The patent is a continuation of patent US 8,282,591 B2, dated October 9th, 2012. The beneficial effect is from March 29th, 2004, which is the date of filing patent 591.

The plaintiffs are in possession of the written description of patent No US 8,747,344 B2 from March 29th, 2004, under specification 35 USC Code § 112(a):

“(a)In General. -

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.”

Merit Medical violated the best mode requirement because the HeRO Graft performs the act of dialysis in the same way as of claimed invention (See Dkt 15 Exhibit A Fig. 1 and Exhibit A Fig. 3)

A copy of the patent-in-suit is attached as Exhibit C.

In a classical arteriovenous shunt (See Dkt. 15, Exhibit B, No.2 Fig. IV) blood flows continuously at a high arterial pressure into the vein, leading to vein damage, neointimal hyperplasia and 80% graft failure within 3 years. Plaintiff overcame this problem by making a venous outflow catheter (No. 12) and connected it to the PTFE graft (No. 11) with a cuff connector disposed about the venous outflow catheter and the arterial graft, making the Hybrid Arteriovenous Shunt (10), (See Dkt 15., Sheet 1 of 3 US Pat No. 8,747,344 B2, Jun.10, 2014). Merit Medical Systems Inc. denies the

problems associated with the classical arteriovenous shunt. Their response is merely baseless and without foundation. The Hon. Court should please rule that Merit is denying the problems associated with the classical arteriovenous shunt because Merit lacks this important medical knowledge.

I. Prior art

Merit Medical Systems Inc. is an assignee of Rafael Squitieri's patent No. US 6,582,409 B1 and US RE 44, 639 E. In both these patents the blood after hemodialysis **goes importantly only into the vein** (See Dkt.15, Exhibit A, Fig. 2). Merit Medical Systems denies that they are an assignee of Squitieri's patent currently (See Dkt 13. p. 7). Merit Medical Systems Inc. uses a metallic connector indisposed within the lumen of the graft and venous outflow catheter. Merit Medical cannot in any manner deny that they are not an assignee of Squitieri's patent.

Hemosphere Inc., who first used the HeRO graft in 2008 was an assignee of Squitieri's patent. Squitieri sold the HeRO graft to CryoLife Inc. in 2012. CryoLife obtained a reissue patent, US RE 44,639 E, dated December 10th, 2013. CryoLife then sold the HeRO graft to Merit Medical Systems Inc. on February 4th, 2016 for \$18,500,000. (See Exhibit D). Merit Medical denies that it paid \$18.5 million to CryoLife. From Cryolife's own website, it clearly announces the sale of the HeRO graft to Merit Medical Inc for \$18.5 million in cash.

In view of the above, it is very clear that Merit Medical Inc. is an assignee of Squitieri's patent and defendant attorneys are making a false statement that Merit Medical did not pay \$18.5 million in cash to CryoLife Inc. (see Exhibit D.)

II. HeRO Graft is an unpatented device. This is an undisputed fact.

The "HeRO" graft means "hemodialysis reliable outflow". This device is used for hemodialysis, that is cleaning of the blood of toxins in kidney failure patients. The HeRO Graft has no patent and no claims. How exactly Hemosphere Inc. made the HeRO Graft is evident from the following:

1. US patent No 8,282,591 B2 was filed on March 29th, 2004, and published under application number 2005/0215938 A1 on Sep. 29, 2005. Hemosphere Inc., looked into the advantages of Khan's Hybrid Arteriovenous Shunt as clearly observed in the diagrams of Fig.1 and Fig. 2, in Sheet 1 and Sheet 2 of the patent publication above (See Exhibit E) that that it has three parts: arterial graft, a cuff connector, and a venous outflow catheter which goes into the right atrium of the heart. Hemosphere Inc., then copied the pending patent 591. Out of the three parts, they copied the arterial graft and the venous outflow catheter and then used the metallic connector of Squitieri's patent indisposed between the arterial graft and venous outflow catheter. Hemosphere Inc., supplied the three parts to different physicians, who were conducting a sponsored study on 36 patients. The device reduced the infection rate by about 60% in patients, compared to traditional dialysis catheters. Hemosphere Inc., then obtained FDA approval in 2008 to use the HeRO graft. They did not mention to the FDA that the HeRO graft has no patent. If they had a patent they would label the patent number on every HeRO supply kit, that was provided to the hospitals for use by the physicians in the operating room.

The defendant attorneys of Merit Medical deny that the HeRO Graft is unpatented (See Dkt 13, p. 26) without mentioning who is the patent owner of the HeRO graft and what is their patent number, violated 35 USC § 287. The fact is Merit Medical Inc., has been using an unpatented device, the HeRO graft, from May 4th, 2016 and continues to use it. The plaintiff has a patented device, US 8,747,344 B2, dated June 10, 2014 which is a continuation of US 8,282,591 B2, dated Oct. 9th 2012. The plaintiff appealed the sanctions imposed by the district court in case No. 1:18-cv-05368 to the United States Court of Appeals case No. 19-1952. Plaintiff was directed by the appeals court to add in the cover sheet "Hospitals and doctors implanting unpatented HeRO Graft to doctors, ET". Appellant court understood that HeRO graft is unpatented device. (See Exhibit F.) In view of the above, HeRo Graft is an unpatented device. Because HeRO Graft is an unpatented device, the plaintiff alleges an affirmative defense that the court should not

allow Merit Medical to use an unpatented device. **The plaintiffs respectfully request the Hon. Court to issue an injunctive order to stop Merit Medical Systems Inc. from making and selling the three parts of the HeRO graft, so that in the future Merit Medical does not abuse its power and authority to take away patented medical devices from the plaintiffs and other patent owners who patent medical devices. Merit Medical is benefiting from the patent of plaintiff. Merit Medical has no patent on HeRO graft and cannot file for non-infringement under statute 35 U.S.C. 295.**

III. Patent validity.

The Khan Hybrid Arteriovenous shunt has two patents: patent US 8,282,591 dated October 9th 2012, and the continuation patent US 8, 347, 344 B2 dated June 10th, 2014.

The parent patent (591) was filed on March 29th, 2004 and the continuation patent (344) has beneficial effect from March 29th, 2004. The two patents are valid under 35 USC 101, 102, and 103. Merit Medical's challenge of the plaintiffs patent validity fails for the following reasons:

1. Both patents are valid under 35 USC, section 101, as is evident from Dkt. 15 (See Exhibit C, pg. 27). Both patents are new and useful inventions. The patents are utility patents and satisfy the requirement under 35 USC, section 101. The Supreme Court in *F. Alice Corp. v. CLS Bank Intl*, 134 S. Ct. 2347 (June 19, 2014) stated that patentable subject matter is determined under 35 USC section 101, which states "whoever invents any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement, thereof, may obtain a patent".

2. 35 USC, section 102 an Anticipated Rejection.

During the prosecution of the reissued application No. 14/509,949, the Patent Trial and Appeal Board differentiated Squitieri's device from patent 591, stating in Khan's patent 591 "blood is deposited into the right atrium of the heart and the cuff

connector connects the venous outflow catheter and the arterial graft”. The patent owner overcome the anticipated rejection.

3. Validity under 35 USC, section 103.

The patent and trademark office issued patent US 8,282, 591 B2 dated October 9th 2020, and differentiated it from Squitieri’s assigned patent by two factors:

- a) The cuff connector is disposed about venous outflow catheter.
- b) Direct deposit of blood in Khan’s hybrid shunt into the right atrium.

In summary, Khan’s two patented devices are thus valid under 35 USC sections 101, 102 and 103.

Merit Medical’s challenge of the validity of Khan’s patent 344 under 35 USC sections 101, 102 and 103 fails (See Dkt. 13 pg. 30).

IV. Patent Term.

Patent 344 was issued on June 10th ,2014, and under US patent law, the patent has a 20-year term. This means the patent validity is through June 10th , 2034. The original patent 591 had a 20-year patent term from March 29th ,2004. The US Patent Board and Trademark office (USPTO) adjusted under 35 USC 154(b) by 1407 days, which is approximately 4 years, so that the total term period extends to 2028. The adjusted period was given because the patent application was prosecuted for 8 years until the patent was issued. Because patent 344 is a continuation patent of patent 591, it retains the patent term of patent 591. Under current patent law, the continuation patent does not change the patent term and retains the patent term of the original patent. Therefore, patent 344 has a term up to 2028. Merit Medical Inc states (Dkt 13 p.4) that the term of patent 344 remains until March 29th 2024, but this does not take into consideration the additional four years of the adjusted period, and therefore the term of patent 344 extends to March 29th , 2028.

V. Failure to State a Claim under Rule 12(b)(6).

The HeRO Graft has no patent and no valid claims. The responsive pleading and the counterclaim fail to state a cause of action under the Twombly and Iqbal standard. Thus, the Hon. Court should respectfully dismiss Merit Medical's responsive pleadings and counterclaim under Rule 12(b)(6).

VI. Dismissal of the Responsive Pleading Answer and Counterclaim under Rule 12(c).

The responsive pleadings and counterclaim failed to state a cause of action because Merit Medical has no patent and no claims, therefore the Hon. Court should please dismiss Merit Medical's Responsive Pleading and Counterclaim under Rule 12(c).

VII. Issuance of Summary Judgement under Rule 56.

The Hon. Court should please issue a summary judgement in favor of the plaintiff, because the defendant has not shown that there is any genuine dispute as to any material fact, with respect to Claim I (Dkt 15 p. 6) literal infringement of claim 13 patent 344 under 35 USC § 112, ¶ 6. Merit Medical has not shown any genuine dispute as to any material fact in claim II (Dkt 15 p. 12), direct infringement under 35 USC § 271(a). Merit Medical has not shown any genuine dispute as to any material fact in claim III (Dkt 15 p. 12), induced infringement under 35 USC § 271(a)(b). Merit Medical has not shown any genuine dispute as to any material fact in claim IV (Dkt 15 p. 12, p. 13), Intentional copying and willful infringement of patent 344. Thus, the plaintiff is entitled to summary judgment as a matter of law.

VIII. Infringement of Claim 13 of Patent 344 under 35 USC § 112 ¶ 6 Equivalent, Means-Plus-Function Limitation.

Legal Standard.

"A means-plus-function limitation contemplated by 35 U.S.C §112 ¶ 6 recites a function to be performed rather than definite structure or materials for performing that

function.” *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1307 (Fed. Cir. 1998); see 35 U.S.C. § 112, ¶ 6 (2006) explaining that “[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof”).

ARGUMENTS

The claimed invention, patent 344 claim 13, is written in means-plus-function limitation under 35 USC §112, ¶ 6 (see Dkt. 15 p. 9). Claim 13 of patent 344, describes a means structure which performs the function of hemodialysis, that is the removal of toxins from the blood of kidney failure patients. Further, in claim 13 the means structure consists of the three parts of patent 344; the arterial graft (No.11), venous outflow catheter (No. 12), and the cuff connector (No. 13) which is disposed about the venous outflow catheter and arterial graft (See Dkt. 15 p. 9). Therefore, all the three parts of the apparatus claim are means to perform the function of hemodialysis (See Dkt. 15 p. 9).

Merit Medical admits the language contained in claim 13 of patent 344 (See Dkt.13, p. 18). Merit admits that Hero Graft “can be used” for hemodialysis, and has three components: arterial graft, titanium connector and venous outflow catheter (See Dkt. 13 p. 11). The titanium connector is indisposed inside the terminal end of the arterial graft and the intake end of the venous outflow catheter. **Merit Medical admits that the HeRO graft performs the hemodialysis function, that is removal of toxins from the blood of the kidney failure patients. Therefore, the claimed function in claim 13 of patent 344 is identical to the function of the HeRO graft.**

The structure described in the specification of patent 344 that performs the act of hemodialysis (See Col 5 Line 45-65) is described in Fig. 2 of the specification. This describes the hemodialysis structure of claim 13 patent 344 (No.10, Fig 2) and

describes the function of how hemodialysis is carried out in the upper extremity, to clear the blood of the toxins in kidney failure patients. The blood is taken from the arterial graft, which is connected to the brachial artery (No. 17), and proceeds to the dialysis machine via a dialysis cannula. Then after that the purified blood is returned to the arterial graft via a dialysis cannula, it is transmitted to the venous outflow catheter by a cuff connector to be deposited into the right atrium of the heart. This meets the statutory requirements under 35 USC § 112 ¶ 6. The specification described structure (Fig. 2) that performs act of hemodialysis diagrammatically depicted (Dkt 15 Exhibit A Fig. 2 p. 23 of 36), diagrammatically depicted (Dkt 15 Exhibit A Fig. 1 p. 18 of 36). Therefore, all the requirements of the literal infringement of claim 13 in patent 344, under 35 USC § 112, ¶ 6 are met. The method of dialysis described in the specification is identical to the method of dialysis described in accused HeRO graft. See Exhibit A Fig 3, comparing to Exhibit A Fig 1 of claimed device (see Dkt 15 p. 18, p. 20).

As stated above in *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1307 (Fed. Cir. 1998), "An element in a claim for a combination may be expressed as a ... means or step for performing a specified function without a recital of structure, material or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specifications and equivalents thereof." In view of the above, claim 13 of patent 344 is a means plus function limitation contemplated by 35 USC § 112, ¶ 6. The HeRO graft performs act of hemodialysis **in exactly the same way** of the claimed invention (See Exhibit. A, Fig 1 and Fig 3).

The structural difference between the claimed invention and accused HeRO graft are in the connector disposition. In the claimed invention, a cuff connector is disposed about the venous outflow catheter and the arterial graft, and in the HeRO graft, a titanium connector is indisposed within the lumen of the graft and the venous outflow catheter (See Dkt. 15 Exhibit A, Fig. 1 and Fig. 3). The function of both connectors, cuff and titanium, are identical. The purified blood after dialysis is transmitted from the

arterial graft to the venous outflow catheter and then deposited into the right atrium of the heart whereby it proceeds eventually to the entire body, which is the final result of the function of dialysis. Merit Medical admits that the blood flows from arterial graft through the titanium connector into the venous outflow catheter (See Dkt. 13 p. 13). Therefore, the function of the connectors is identical, irrespective of the disposition of the connectors. **Such a change is, therefore, insubstantial**, meeting the statutory requirement of 35 USC § 112, ¶ 6.

In summary, there is a functional identity and structural equivalency between the claimed invention and accused HeRO graft. **The HeRo graft literally infringes upon claim 13 of patent 344 under 35 USC § 112, ¶ 6 under means-plus-function limitation as stated in 35 USC § 112 ¶ 6, under the insubstantial difference test, the function is identical between the cuff connector and the titanium connector, because the blood is transmitted in both from the arterial graft to the venous outflow catheter. The titanium connector of the accused device and the cuff connector of the claimed device are equivalent under USC 35 § 112, ¶ 6, “equivalent”.**

Under a modified version of the function-way-result methodology described in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 608, 85 USPQ 328, 330 (1950), two structures may be "equivalent" for purposes of § 112, ¶ 6 if they perform the identical function, in substantially the same way, with substantially the same result. See *Odetics*, 185 F.3d at 1267, 51 USPQ2d at 1229-30 (setting forth a modified function-way-result analysis, acknowledging that "this tripartite test developed for the doctrine of equivalents is not wholly transferable to the § 112, ¶ 6 statutory equivalence context" due to the functional identity requirement).

IX. Doctrine of equivalency.

Plaintiff did not claim any remedy under doctrine of equivalency; however, the defendant attorney of Merit Medical brings doctrine of equivalency estoppel to bar cuff

connector. Defendant attorney of Merit Medical failed to understand that plaintiff's claim is under literal infringement 35 USC § 112, ¶ 6. The doctrine of equivalency estoppel does not apply. The restrictions placed on the doctrine of equivalence by Festo will not apply. The plaintiff amended his complaint during the prosecution of patent US 8, 282, 591 B2 adding cuff connector disposed about the arterial graft and venous outflow catheter. That differentiated the claimed invention from the prior art of Rafael Squitieri's patent under patent rules, if applicant amends a means-plus-function claim element for the purpose of patentability, the claim element will nevertheless be entitled to its equivalents under 35 USC § 112, ¶ 6. Therefore, the defendant attorney of Merit Medical has no reason to claim doctrine of equivalency to bar cuff connector disposed about arterial graft and venous outflow catheter under defendant's titanium connector, that is indisposed between the arterial graft and the venous outflow catheter. Plaintiff requests the honorable court to deny defendants' estoppel under doctrine of equivalency.

Legal standard

In the doctrine of equivalency there are three prongs: the function has to be substantially equivalent to be performed substantially in the same way and produce a substantially same result (F.W.R.). Under first prong, the function is identical. § 112 ¶ 6 equivalence is determined by applying the truncated "way-result" test, since the functional identity is a prerequisite in the determination of literal infringement analysis of a means-plus-function claim. The way is substantially the same and the result is substantially the same. The test is truncated as function way. This tripartite test of doctrine of equivalents is not wholly transferable to the § 112, ¶ 6 statutory equivalence context due to the functional identity requirement. See *Odetics*, 185 F.3d at 1267, 51 USPQ2d at 1229-30. (See Dkt 15 p. 11). Merit Medical brings doctrine of equivalent estoppel of titanium connector, which is irrelevant, because the function of both connectors is identical and the structural differences are insubstantial. Because § 112 ¶ 6 equivalents analysis is performed under the mantle of literal infringement, the

restrictions placed on the doctrine of equivalents by Festo will not apply. Thus, even if the applicant amends a means-plus-function claim element for the purpose of patentability, that claim element will nevertheless be entitled to its “equivalents” under § 112, ¶ 6.

Merit Medical responded to Plaintiff’s legal standard under 35 USC § 112 ¶ 6 “An element in a claim for a combination may be expressed as a ... means or step for performing a specified function without a recital of structure, material or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specifications and equivalents thereof.” (see Dkt 13 p. 15) that an allegation is a legal conclusion and does not require a response. Merit Medical has to act and respond within the framework of statute. The response is therefore baseless, mere conclusory, without foundation. The Honorable court should rule that Merit response is baseless and unpersuasive.

In Dkt 15 p. 6 it is stated: “If an accused structure is not a section 112, paragraph 6 equivalent of the disclosed structure because it does not perform the identical function of that disclosed structure and hence does not literally infringe, it may nevertheless still be an “equivalent” under the doctrine of equivalents. Thus, if one applies the traditional function-way-result test, the accused structure must perform substantially the same function, in substantially the same way, to achieve substantially the same result, as the disclosed structure (See *Dawn Equip. Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1016, 46 USPQ2d 1109, 1113 (Fed. Cir. 1998). A key feature that distinguishes “equivalents” under section 112, paragraph 6 and “equivalents” under the doctrine of equivalents is that section 112, paragraph 6 equivalents must perform the identical function of the disclosed structure, see *Odetics*, 185 F.3d at 1267, 51 USPQ2d at 1229; *Pennwalt*, 833 F.2d at 934, 4 USPQ2d at 1739, while Case 2:21-cv-00337-CMR Document 15 Filed 07/28/21 Page 9 of 36 equivalents under the doctrine of equivalents need only perform a substantially similar function, see *Al-Site Corp. v. VSI Intl, Inc.*, 174 F.3d 1308, 1320-21, 50 USPQ2d 1161, 1168 (Fed. Cir. 1999)”. In claimed invention the equivalent cuff

connector disposed about graft and venous outflow catheter performs identical function of accused HeRO graft where the titanium connector is indisposed between the graft and venous outflow catheter, in both blood after purification is transmitting from the graft to the venous outflow catheter in identical way (See Dkt 15 Exhibit A Fig. 1 and Exhibit A Fig. 3).

Merit Medical responded (see Dkt 13 p. 16) that no response is required because these are legal conclusions, which is not the fact. This is a legal framework, which the plaintiff is using in determination that claim 13 of patent 344 is literally infringed under 35 USC § 112 ¶ 6. Merit Medical response is baseless, conclusory, unreasonable, without foundation. The Honorable court should declare Merit's response as unpersuasive.

The plaintiff contended in Dkt 15 p. 8: "Because the "way" and "result" prongs are the same under both section 112, paragraph 6 and the doctrine of equivalents test, a structure failing the section 112, paragraph 6 test under either or both prongs must fail the doctrine of equivalents test for the same reason(s). That was the case in Chiuminatta, in which the "way" was determined to be substantially different under a section 112, paragraph 6 analysis (See Chiuminatta, 145 F.3d at 1309, 46 USPQ2d at 1757). Accordingly, we concluded that the accused structure did not infringe under the doctrine of equivalents for precisely the same reason (See id. 1311, 46 USPQ2d. 17 58)."

The defendant responded in Dkt 13 p. 16 and named this as paragraph 16 of the complaint did not provide response stating paragraph 16 is a legal conclusion. That is wrong. The paragraph provides statutory requirements under 35 USC paragraph 6, means-plus-function limitations, and also describes the requirements under doctrine of equivalency and 35 USC 112 paragraph 6 equivalence. The defendant attorney had to respond to paragraph 16 of the complaint. Refusal to respond amounts to admission of the facts described in paragraph 16 of the complaint. The response is unpersuasive. The Honorable court should rule that defendants' response is unpersuasive.

The plaintiff contended in Dkt 15 p. 8 “Because the function is identical in both the accused HeRO graft, and the claimed invention, the structural differences are insubstantial with respect to the connector, therefore claim 13 of patent 344 is being infringed upon by the accused HeRO graft under 35 USC section 112, paragraph 6 - means plus function limitation.” The defendant Merit Medical treated it as paragraph 17 and denied the allegations. Merit Medical intentionally is not responding to the allegations because the contents of the paragraph 17 are under infringement of 35 USC 112 paragraph 6.

In view of the foregoing, defendant Merit Medical is avoiding response to the literal infringement of claim 13 of patent 344 under 35 USC 112 paragraph 6 under means-plus-function limitation, and insubstantial structural difference of the connector disposition.

The plaintiff therefore prays that honorable court declare accused HeRO graft infringed claim 13 of patent 344 under means-plus-function limitation, identical function and structural equivalency, under structural insubstantial test, and award the relief requested in the complaint.

VII. Intentional copying and willful infringement of patent 344.

Plaintiff alleged (Dkt 15 p. 12) that Merit Medical willfully copied venous outflow catheter, described as No. 12 in Fig. 2 of patent 344, in the manufacture of HeRO graft (See Dkt 15 Exhibit A Fig. 3 p. 20 of 36, p. 21 of 36) Under two assigned patents of Merit Medical Systems Inc., the venous outflow catheter remains in the vein (see Dkt 15 Exhibit A Fig. 2). This constitutes willful copying and willful infringement. Further, Merit Medical copied the structural dimensions of the graft, of the HeRO graft is 6mm in diameter, that implies the inner diameter of the graft. Venous outflow catheter of Merit Medical is 5 mm in inner diameter. In the specification as described in column 4 p. 30 of patent (344), flexible graft No. 11 measures 6 to 8 mm, and the venous outflow catheter (12) has a smaller diameter: 1 mm than the graft. The diameter

of venous outflow catheter is 5 mm. These structural dimensions were copied by the merit medial in the manufacture of HeRO graft. **HeRO graft has no patent, no valid claims.** In the assigned patents there is no mention of structural dimensions of 6 mm graft and 5 mm venous outflow catheter. Therefore, Merit Medical copied the structural diameters of the patented invention (344) and also venous outflow catheter No. 12.

Defendants' response (Dkt 13 p. 26).

Merit admits that Plaintiff seeks damages of \$2,000,000. Merit denies it has copied Plaintiff's invention, but does not provide any evidentiary reason why they used venous outflow catheter to reach to the right atrium and why they used 6 mm graft and 5 mm venous outflow catheter. Preponderance of evidence shows Merit copied venous outflow catheter (12) and the structural diameters of 6 mm graft and 5 mm venous outflow catheter. Merit Medical brings infringement of claim 13 of patent 344 and doctrine of equivalency in their defense of willful copying of claim IV, which is irrelevant. The plaintiff therefore is entitled for \$2,000,000 damages. If plaintiff prevails, the court should triple the damage.

VIII. Plaintiff seeks \$6,000,000 damage for infringement of claim 13 of patent (344) under 35 USC § 112 ¶ 6 from Merit Medical Systems Inc.

Defendants' response (Dkt 13 p. 25).

Merit admits Plaintiff seeks \$6,000,000, but denies infringement of claim 13 of patent 344. This issue will be resolved by the court and the court will rule on the infringement issue. If plaintiffs prevail, they will be entitled to more than \$6,000,000 in damages.

IX. Direct infringement of claim 2 under 35 USC Section 271(a).

Plaintiff alleged Merit Medical Systems Inc. is making and selling the hybrid arteriovenous shunt of patent 344 as the unpatented HeRO graft from February 4th, 2016 and continues to make and sell the HeRO graft, thereby infringing upon patent

under 35 USC section 271 (a), direct infringement. Merit Medical Systems Inc., is liable for damages. The Plaintiffs seek relief of \$2,000,000 from Merit Medical Systems Inc. for direct infringement under 35 USC, section 271 (a).

Defendants' response (Dkt 13 p. 25)

Merit admits it has made and sold and continues to make the HeRO graft, but denies it has infringed 35 USC section 271(a). Defendant brings infringement of claim 13 of the patent (344) in their defense, which is irrelevant. The claim is a liability infringement claim, not a literal infringement claim.

Damages under 35 USC 271(a) are for making and selling the unpatented HeRO graft, which amounts to making and selling the patented Khan's hybrid shunt of patent (344), and therefore violates claim II of the complaint under 35 USC section 271(a). Plaintiff is entitled to damages of \$2,000,000.

X. Plaintiff alleged Induced Infringement under 35 USC section 271(b). (Dkt 15 p. 12)

Merit Medical Systems was selling the 3 parts of the unpatented HeRO graft to hospitals for making the HeRO graft by the hospital's physicians to implant the HeRO graft into patients. The plaintiffs seek damages of \$2,000,000 from Merit Medical Systems Inc. for induced infringement of patent 344, under 35 USC section 271(b).

Defendants' response (Dkt 13 p. 26)

Merit admits it has sold and continues to sell the HeRO graft and denies HeRO graft is an unpatented device.

The fact of the matter is that HeRO graft is an unpatented device with no patent number. Merit Medical continues to sell the three parts of the HeRO graft to the hospitals. The hospital is a customer of Merit Medical. That constitutes induced infringement. Merit Medical sells the three parts of HeRO graft in a kit with no patent number on the kit, because Merit has no patent on HeRO graft. The physicians of the

hospitals make HeRO graft by combining the three parts and implanting on the chronic kidney failure patients. **The hospital physicians are not the customers of Merit Medical.** By definition customer is a person who buys a product from the seller. The hospital physicians do not buy the three parts of the HeRO graft. Merit is a source of supplying the three parts to the hospital, but the physicians make and implant HeRO graft. Therefore, the Plaintiff is entitled to seek damages of claim III of the complaint for \$2,000,000 and court should grant Plaintiff's damages for induced infringement.

XI. Plaintiff's response to additional defenses 1-10 of the defendant.

FIRST DEFENSE: "Complaint fails to state a claim upon which relief can be granted"

PLAINTIFF'S RESPONSE: Plaintiff has valid I-IV claims (See Dkt 15 p. 6, p. 12).

Defendant Merit Medical has no valid claims to state a cause of action, therefore plaintiff requests the court to dismiss defendant's responsive pleading and counterclaims under rule 12(b)(6).

Plaintiff requests the court to dismiss defendant's responsive pleading and counterclaim (Dkt 13) under rule 12(c) because defendants have failed to state a valid claim for the cause of action.

SECOND DEFENCE: "Merit does not infringe and has not infringed, directly, indirectly, by contribution, by inducement, willfully or otherwise, any valid, enforceable claim of the '344 patent, either literally or under the doctrine of equivalents"

PLAINTIFF'S RESPONSE: the Plaintiff alleges that the defendant Merit Medical directly violated 35 USC section 271(a) by supplying the HeRO kit which contains the three parts of HeRO graft. Also, indirectly infringed 271(b). The induced

infringement by supplying the HERO graft parts to the hospital. Further, Merit Medical infringed claim 13 of patent (344). The doctrine of equivalence restrictions does not apply under Festo.

THIRD DEFENSE: “The claims of the '344 patent are invalid for failure to comply with the conditions of patentability set forth in 35 U.S.C. § 101 et seq.”

PLAINTIFF’S RESPONSE: The Plaintiff made it clear (evident from Dkt 15 Exhibit C) that patent (344) was documented by the PTO as a useful new invention, satisfying the requirement of 35 USC section 101.

FORTH DEFENSE: “Plaintiffs’ claims are barred by the doctrine of prosecution history estoppel based on statements, representations, amendments, and admissions made during the prosecution of the '344 patent and its related applications.”

PLAINTIFF’S RESPONSE: The plaintiff contends that the prosecution history estoppel applies to the claims under doctrine of equivalent, but not to the literal infringement claim, claim 13 of 35 USC ¶ 6. The defendants’ argument is irrelevant under law and cannot bar the plaintiff’s claims under prosecution history of estoppel under Festo.

FIFTH DEFENSE: “Plaintiffs’ claims for damages for alleged infringement of the '344 patent are limited or barred by 35 U.S.C. §§ 286 and/or 287.”

PLAINTIFF’S RESPONSE:

The Plaintiff response to 35 USC section 286 that the infringement lawsuit was filed within the statute of limitation of six years. Plaintiff is entitled to file lawsuit against Merit Medical until February 4th 2022, because the date of infringement began

on February 4th 2016. Therefore, infringement of patent 344 is not barred by 35 USC § 286.

The Plaintiff response to 35 USC section 287: the defendant Merit Medical supplied the HeRO kit to hospitals for implanting the HeRO graft to the patients, and this kit has no labeling of patent number. The defendant violated 35 USC section 287 because the HeRO graft is unpatented.

In conclusion, 35 U.S.C. §§ 286 and/or 287 cannot bar the plaintiff's claims I-IV of the complaint.

SIXTH DEFENSE: "Plaintiffs are barred by 35 U.S.C. §288 from recovering any costs associated with this action."

PLAINTIFF'S RESPONSE: Claims I-IV of the complaint (Dkt 15) are valid claims under 35 U.S.C. §288. The plaintiff is entitled for relief, therefore the bar under 35 U.S.C. §288 does not apply.

SEVENTH DEFENSE: "Plaintiffs' conduct in bringing this action and their course of conduct relative to Merit violates Rule 11 of the FRCP, 28 U.S.C. § 1927 and is exceptional under 35 U.S.C. § 285. Merit is entitled to its fees and costs in defending Plaintiffs' frivolous claims."

PLAINTIFF'S RESPONSE: The plaintiff alleges that Merit Medical violated FRCP Rule 11 by bringing frivolous claims, violating Rule 11(b), Rule 11(b)(1), Rule 11(b)(2), Rule 11(b)(3). Defendant Merit Medical knew that the HeRO graft is an unpatented device, with no claims, violating Rule 11(b), also violated b(1) for harassment, misuse of judicial process, by prolonging the litigation. Violated b(2) because Merit Medical has no meritorious claims and also violates b(3) for not providing evidentiary evidence in support of their claims. The plaintiff's claims I-IV are

meritorious under rule 12(b)(2), patented, have evidentiary evidence under 35 USC § 101, satisfying requirement under rule 11(b)(3). Further, plaintiff's claims I-IV are valid claims of patent 344, satisfying the requirement under rule 11(b). The plaintiff contends Merit Medical attorney and Merit Medical should be sanctioned under rule 11, for violating rule 11(b)(1) because the actions are vexatious, intended for harassment of the plaintiff. The Merit's claims are frivolous, unreasonable, without foundation. Plaintiff is entitled for the fees and cost incurred in defending Merit Medical's cost from defendant attorney and Merit Medical in defending frivolous claims of Merit Medical.

In Chicago litigation 1:18-cv-05368 Merit Medical through its defendant attorney Brent Lorimer got plaintiff sanctioned for \$95,966.90 for improper venue and service. Plaintiff had sued 300 defendant physicians for patent 344 infringement for making the HeRO graft from the three components of HeRO graft. Out of 300 defendant physicians Merit Medical indemnified 110 physicians from different states of the US, who filed motion for sanctions against plaintiff. The list is attached (Exhibit G). Defendant attorney tried very hard to make the plaintiff withdraw the case. Plaintiff Nazir Khan was fighting for the patent infringement, refused to withdraw the case. Merit Medical and defendant attorney filed for sanctions under rule 11. The court sanctioned the plaintiff for \$95,966.90. When Plaintiff appealed the case to the Federal Circuit court under docket 2019-1952 he had to put a cash bond of the same amount with the clerk of the District court for Northern Illinois. Plaintiff paid the cash bond from his pension fund. The United States Court of Appeals for the Federal Circuit affirmed the decision of district court. The case was appealed to Supreme court in the writ of Certiorari. The Supreme court refused to hear the case. The plaintiff lost \$95,966.90. If the plaintiff prevails in the present litigation in the District Court of Utah, where the service and venue is proper, plaintiff wants Merit Medical to pay the plaintiff \$500.000 from each indemnified physician to the plaintiff for infringement under 35 USC §271(a), §271(c).

Plaintiff requests the court to sanction Merit Medical and defendant attorney Brent Lorimer under rule 11(c) for bringing frivolous claims, which are unreasonable, without foundation.

Plaintiff requests the court to sanction defendant attorney Brent Lorimer under 28 USC § 1927 for abuse of litigation process, bringing frivolous claims, and pay cost to the plaintiff for defending Merit's frivolous claims.

Response to 35 USC § 285: Merit is not entitled to any cost as exceptional under 35 USC § 285. Merit's claims are frivolous and meritless. In Chicago litigation in Northern District of Illinois case No. 1:18-cv-05368 United States District Judge Virginia M. Kendall denied the Merit's claim under 35 USC § 285. Under supreme court's decision in Octane Fitness, LLC vs ICON health and fitness, Inc. 134 S Ct. 1749 (April 29, 2014), Supreme Court stated that a case should be declared exceptional in only two circumstances: (1) "when there has been some material inappropriate conduct," and (2) "when the litigations is both brought in subjective bad faith and objectively baseless." The district court judge in Chicago stated that Merit's case is not exceptional to award attorney's fees under 35 USC § 285. Defendant had claimed attorney's fees for \$292,693.00. The district court judge stated to declare a case exceptional is the district court's discretion and denied the attorney's fees of Merit Medical attorney Brent Lorimer under Supreme court ruling in Octane Fitness, LLC vs ICON health and fitness, Inc. 134 S Ct. 1749 (April 29, 2014). The defendant Merit Medical filed a counterclaim to the United States Court of Appeals for the federal circuit under docket 1952, that was denied by the United States Court of Appeals for the federal circuit. The Federal Circuit affirmed the decision of the district court under rule 11 sanctions for improper venue and service. The case went to supreme court in the writ of Certiorari. Supreme court refused to hear the case. The defendant attorney's claims are frivolous, unreasonable, without foundation. Court should sanction Merit Medical's attorney Brent Lorimer under 35 USC § 285.

EIGHTH DEFENSE: “Plaintiffs’ claim for injunctive relief is barred because they do not manufacture or sell the claimed invention and have not and cannot establish irreparable harm.”

PLAINTIFF’S RESPONSE: Plaintiff alleges that the court should provide permanent injunctive relief so that Merit Medical does not copy patented medical invention (344) of the plaintiff and prevent Merit Medical from copying medical devices from other doctors in future who have patented their medical devices. Plaintiff patented patent (344), and that device was used by Merit Medical in the name of HeRO graft. HeRO graft is an unpatented device, used all over the United States, and in Europe. Plaintiff deserves an injunctive relief and stop Merit Medical from making the unpatented HeRO graft. Plaintiff is entitled for permanent injunction under Rule 35 USC Section 295 because the Merit Medical has not shown any evidence of patent on accused device Hero Graft. Plaintiff is in process of manufacturing and selling patented hybrid arteriovenous shunt under patent number (344), (591). Plaintiff paid \$7000 to Brokerage firm “Bank of IP” 17745 Metcalf Avenue, Building 1, Stilwell, Kansas 66085 USA. Plaintiff is still waiting for the manufacturer to make claimed Hybrid arteriovenous shunt.

NINTH DEFENSE: “Plaintiffs’ claim for willfulness is barred because the Complaint fails to state facts sufficient to make out a claim for willfulness. Merit has conducted itself in good faith, precluding a finding of willfulness.”

PLAINTIFF’S RESPONSE: Plaintiff has provided enough evidence in claim IV (Dkt 15 p. 12) for willful infringement of patent (344). Defendants’ claim to bar willful infringement is irrelevant, meritless, and therefore plaintiff is entitled for relief under willful infringement. If plaintiff prevails, the court should triple the damage.

TENTH DEFENSE: “Merit reserves the right to add additional defenses upon discovery of information bearing on the claims in Plaintiffs' Complaint.”

PLAINTIFF'S RESPONSE: Plaintiff does not need to answer this at this time.

COUNTERCLAIMS

FIRST COUNTERCLAIM

Declaratory Judgement of Non-Infringement

Plaintiffs' response:

Merit Medical has infringed claim 13 of patent (344) under 35 USC §112 ¶ 6 discussed earlier in the arguments. The patent is valid under 35 USC 101, 102, 103. Merit has infringed patent 344 directly and indirectly under 35 USC 271(a) and 271(b) as discussed earlier. Merit's claims of non-infringement are baseless and meritless. The honorable court should declare that Merit Medical Inc has infringed claim 13 of patent (344) under 35 USC §112 ¶ 6 and also infringed 35 USC §271(a) and 35 USC §271(b). Merit cannot claim for noninfringement, because the HeRO Graft is an unpatented device. Therefore, under 35 USC 295 Merit cannot claim non-infringement.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity

“12. Merit re-alleges and incorporates by this reference the content of paragraphs 1-11 of this Counterclaim as though set forth fully herein.

13. As interpreted by Plaintiffs, one or more claims of the '344 patent are invalid for failure to comply with one or more requirements for patentability under the patent laws of the United States, including, but not limited to, 35 U.S.C. §§ 102, 103 and/or 112.

14. Specifically, if any of the claims of the '344 patent as interpreted by Plaintiffs is found to be infringed, such claims are invalid in light of the prior art under 35 U.S.C. §§ 102 and/or 103.

WHEREFORE, Merit prays for judgment as set forth hereinafter”

Plaintiffs’ response:

Plaintiffs contended in the arguments (p. 4, p. 5 of the response) that patent 344 is valid under 35 USC section 102 and 103. The defendant Merit Medical has no reason to make plaintiff’s infringement claim invalid under 35 USC section 102 or 103.

Therefore, Merit cannot claim any judgement based on invalidity of patent (344).

THIRD COUNTERCLAIM

Interference with Economic Relations

Plaintiffs’ response:

Plaintiffs sued 300 defendant physicians in Chicago Litigation for infringement of patent 344. Out of the 300 (See Exhibit G), Merit indemnified 110 physicians who got plaintiff sanctioned under Rule 11. The defendant physicians across the United States had infringed patent 344 for making accused HeRO graft under 35 USC 271(a) and also under 35 USC 271(c) for using Plaintiff’s venous outflow catheter (12) in making the accused HeRO graft. The defendant physicians are not the customers of Merit Medical. They have not purchased the accused HeRO graft from Merit Medical. Therefore, the plaintiff has not interfered with economic relationship of the Merit Medical and its customers. Merit Medical has made a false claim that plaintiff was intimidating merit customers, frightening them into ceasing purchases of accused HeRO graft, and driving a wedge between Merit and its customers. **The fact of the matter is very clear that defendant physicians are not customers.** They are independent physicians and therefore the plaintiff has not frightened them from purchasing the accused HeRO graft. Merit Medical is making a false statement. Defendant Merit Medical is making a false statement of interference of economic relationship between Merit and its customers. The fact is the physicians are not Merit Medical’s customers. Plaintiff was seeking relief

under 35 USC 271(a), 271(c) for implanting unpatented HeRO graft into the patients with chronic kidney disease. The allegation is, therefore, false. The court should sanction Merit Medical for making false allegations.

The court should deny the prayer of the counterclaim. There is no legal basis for any relief of the counterclaim.

Conclusion

In conclusion, Merit Medical has infringed Claim I of the complaint (Dkt 15) for infringing Claim 13 of patent 344 for literal infringement under 35 USC § 112 ¶ 6 under means-plus-function limitation, insubstantial structural difference test, estoppel of doctrine of equivalency is improper, Merit Medical has violated 35 USC § 271(a) for making and selling the HeRO graft. Claim II of the complaint (Dkt 15) for direct infringement. Violated Claim III of the complaint (Dkt 15) for induced infringement under 35 USC § 271 (b). Violated Claim IV of the complaint (Dkt 15) for intentional copying and willful infringement of patent (344).

Honorable court should make a declaratory judgement that the responsive pleading answer and counterclaim be dismissed under rule 12(b)(6), rule 12(c). The Honorable Court should order summary judgment in favor of plaintiff under rule 56 because there is no material issue of facts in claims I, II, III and IV.

RELIEF

The plaintiffs respectfully pray for the following relief, as mentioned in the complaint (Dkt 15):

1. Literal infringement of patent 344 under section 112 para 6 for more than \$6,000,000 as compensatory damages.

2. Direct infringement of patent 344 under 35 USC section 271 (a) for \$2,000,000.

3. Induced infringement of patent 344 for \$2,000,000.

4. Copying and willful infringement of patent 344 for \$2,000,000. If the plaintiffs win, the Hon. Court may triple the damages to \$6,000,000.

5. Merit Medical Inc., should pay royalty fee of 10% from all the HeRO grafts that they have sold after February 4th, 2016 and retrospectively from the date of publication of patent (344) US2014/0100508 A1 dated April 10th 2014.

6. Punitive damages of \$2,000,000.

7. Permanent injunction to stop the manufacture and sale of the HeRO graft device.

Respectfully submitted,

/s/ Nazir Khan

/s/ Iftikhar Khan

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Dated 8/18/2021

Nazir Khan, Iftikhar Khan v. Merit Medical Systems, Inc.

Certificate of Service

This is to certify that Responsive amended complaint to answer and counterclaims was sent by mail on 8/18/2021, and further the court should electronically send the document to the defendant attorneys:

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Dated 8/18/2021